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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Legislation and Regulation Committee

Andrea Zinder, Board Member and Chair
Tim Dazé, Board Member
Hank Hough, Board Member
Ken Schell, PharmD, Board Vice-President

LEGISLATION REPORT

5. Introduced Legislation Related to the Practice of Pharmacy

The Legislature reconvened on January 3, 2007. As of January 17, 2007, no bills have been introduced affecting relevant Business and Professions Code Section.

A copy of the Legislative calendar for 2007 is in Attachment 1.

6. Proposed Legislation – BOARD ACTION REQUIRED

a. Omnibus Provisions

Recommendation: Approve each of the following omnibus provisions for board sponsorship in 2007.

All of the following provisions should be omnibus provisions for 2007. Copies of the exact language follows in Attachment 2.

(1) Sections 4162 and 4162.5
Extend bonding requirements for wholesalers from 2011 to 2015 to match the extension given to implement the e-pedigree requirements, restoring provisions in SB 1476 chaptered out by SB 1475.

(2) Sections 4314 and 4315
Allow the board to cite and fine licensees for violations of Health and Safety Code sections 150200-150206 which authorize a county to establish by local ordinance, a repository and distribution program for specified unused medications from skilled nursing homes to medically indigent patients served by government-owned pharmacies.

(3) Section 4084
To allow board inspectors to embargo a prescription drug when the inspector has probable cause that it is misbranded.

(4) Sections 4160(f) – 4161(k)
Revise section to specify temporary license fee of $550. Current law does not specify the temporary fee.

(5) Section 4208
Revise requirements for intern licenses to allow the board the discretion to extend the duration of an intern license.

Board staff anticipate the Business Professions and Economic Development Committee will author the 2007 omnibus bill of the Department of Consumer Affairs.

b. Proposed changes to AB 2986 (Chapter 286, Statutes of 2006)

RECOMMENDATION: Approve Modifications to new CURES Requirements Enacted by AB 2986

Last year AB 2986 changed the reporting requirement for CURES, expanded reporting to include Schedule IV controlled substances and added elements that must be entered into CURES (e.g., the patient phone number and number of refills). Specifically, C-IIs, IIIs, and IVs now must be submitted weekly to Atlantic Associates.

However, staff is also recommending a specific amendment to mandate a January 1, 2008, "drop dead date" for aggressive enforcement, as well as a requirement for prescribers to use of the new security prescription forms that contain the new data fields, also by January 1, 2008 (essentially by making the current security forms obsolete).

A draft of the proposed revisions is included in Attachment 3. Staff at the Department of Justice supports this proposal.

The board will monitor compliance with AB 2986 requirements during 2007 inspections and is encouraging pharmacies to work with their software vendors to ensure compliance as quickly as possible.

Also included with the packet are the Meeting Summary of the January 8, 2007 Meeting, Meeting Summary of the October 25, 2006 Meeting, and Second Quarterly Report on Committee Goals for 2006/2007.

ATTACHMENT 1

Tentative Legislative Calendar 2007-08
Regular Session

TENTATIVE LEGISLATIVE CALENDAR 2007–08 REGULAR SESSION

2007

Jan. 1	Statutes take effect (Art. IV, Sec. 8(c)).
Jan. 3	Legislature reconvenes (J.R. 51(a)(1)).
Jan. 10	Budget Bill must be submitted by Governor (Art. IV, Sec. 12(a)).
Jan. 26	**Last day to submit bill requests to Office of Legislative Counsel.**
Feb. 23	Last day for bills to be introduced (J.R. 61(a)(1), (J.R. 54(a))
Mar. 29	Spring Recess begins upon adjournment (J.R. 51 (a)(2)).
Apr. 9	Legislature reconvenes from Spring Recess (J.R. 51(a)(2)).
Apr. 27	Last day for policy committees to hear and report fiscal bills for referral to fiscal committees (J.R. 61(a)(2)).
May 11	Last day for policy committees to hear and report to the floor non–fiscal bills (J.R. 61(a)(3)).
May 25	Last day for policy committees to meet prior to June 11 (J.R. 61(a)(4)).
June 1	Last day for fiscal committees to hear and report bills to the floor (J.R. 61(a)(5)). Last day for fiscal committees to meet prior to June 11 (J.R. 61(a)(6)).
June 4	Through June 8 – Floor session only. No committee may meet for any purpose. (J.R. 61(a)(7)).
June 8	Last day to pass bills out of house of origin (J.R. 61(a)(8)).
June 11	Committee meetings may resume (J.R. 61(a)(9)).
June 15	Budget Bill must be passed by midnight (Art. IV, Sec. 12(c)).
July 13	Last day for policy committees to hear and report bills (J.R. 61(a)(10)).
July 20	Summer Recess begins upon adjournment, provided Budget Bill has been passed (J.R. 51(a)(3)).
Aug. 20	Legislature reconvenes from Summer Recess (J.R. 51(a)(3)).
Aug. 31	Last day for fiscal committees to meet and report bills to the Floor (J.R. 61(a)(11)).

TENTATIVE LEGISLATIVE CALENDAR – REGULAR SESSION—Continued

Sept. 3	Through Sept. 14 – Floor session only. No committee may meet for any purpose (J.R. 61(a)(12)).
Sept. 7	Last day to amend on the Floor (J.R. 61 (a)(13)).
Sept. 14	Last day for any bill to be passed (J.R. 61(a)(14)). Interim Recess begins upon adjournment (J.R. 51(a)(4)).
Oct. 14	Last day for Governor to sign or veto bills passed by the Legislature on or before Sept. 14 and in the Governor's possession after Sept. 14 (Art. IV, Sec. 10(b)(1)).

2008

Jan. 1	Statutes take effect (Art. IV, Sec. 8(c)).
Jan. 7	Legislature reconvenes (J.R. 51(a)(4)).

ATTACHMENT 2

Language for Omnibus provisions

Board of Pharmacy
2007 Omnibus Bill Proposed Language

B&P 4084 Adulterated or Counterfeit Drug or Dangerous Device

Amend Section 4084 of the Business and Professions Code, to read:

B&P 4084. (a) When a board inspector finds, or has probable cause to believe, that any dangerous drug or dangerous device is adulterated, misbranded, or counterfeit, the board inspector shall affix a tag or other marking to that dangerous drug or dangerous device. The board inspector shall give notice to the person that the dangerous drug or dangerous device bearing the tag or marking has been embargoed.
(b) When a board inspector has found that an embargoed dangerous drug or dangerous device is not adulterated, misbranded, or counterfeit, a board inspector shall remove the tag or other marking.
(c) A board inspector may secure a sample or specimen of a dangerous drug or dangerous device. If the board inspector obtains a sample prior to leaving the premises, the board inspector shall leave a receipt describing the sample.
(d) For the purposes of this article "counterfeit" shall have the meaning defined in Section 109905 of the Health and Safety Code.
(e) For the purposes of this article "adulterated" shall have the meaning defined in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.
(f) For the purposes of this article "misbranded" shall have the meaning defined in Article 3 (commencing with Section 111330) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

B&P 4162 & 4162.5 Wholesaler License Surety Bond Requirements

Amend Sections 4162 and 4162.5 of the Business and Professions Code to read:

4162. (a) (1) An applicant, that is not a government owned and operated wholesaler, for the issuance or renewal of a wholesaler license shall submit a surety bond of one hundred thousand dollars ($100,000) or other equivalent means of security acceptable to the board payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.
(2) For purposes of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars ($100,000) if the annual gross receipts of the previous tax year for the wholesaler is ten million dollars ($10,000,000) or less, in which case the surety bond shall be twenty-five thousand dollars ($25,000).
(3) A person to whom an approved new drug application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application, and is licensed or applies for licensure as a wholesaler, shall not be required to post a surety bond as provided in paragraph (1).
(4) For licensees subject to paragraph (2), or (3), the board may require a bond up to one

hundred thousand dollars ($100,000) for any licensee who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.
(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days after the order imposing the fine, or costs become final.
(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.
(d) This section shall become operative on January 1, 2006, and shall remain in effect only until January 1, ~~2011~~ 2015, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, ~~2011~~ 2015, deletes or extends those dates.

4162.5. (a) (1) An applicant for the issuance or renewal of a nonresident wholesaler license shall submit a surety bond of one hundred thousand dollars ($100,000), or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.
(2) For purpose of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars ($100,000) if the annual gross receipts of the previous tax year for the nonresident wholesaler is ten million dollars ($10,000,000) or less in which the surety bond shall be twenty-five thousand dollars ($25,000).
(3) For applicants who satisfy paragraph (2), the board may require a bond up to one hundred thousand dollars ($100,000) for any nonresident wholesaler who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.
(4) A person to whom an approved new drug application or a biologics license application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application or biologics license application, and is licensed or applies for licensure as a nonresident wholesaler, shall not be required to post a surety bond as provided in this section.
(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or when the costs become final.
(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.
(d) This section shall become operative on January 1, 2006, and shall become inoperative and is repealed on, January 1, ~~2011~~ 2015, unless a later enacted statute, that is enacted before January 1, ~~2011~~ 2015, deletes or extends those dates.

B&P 4314 & 4315 Cite and Fine, Letter of Admonishment

Amend Sections 4314 and 4315 of the Business and Professions Code, to read:

4314. (a) The board may issue citations containing fines and orders of abatement for any violation of Section 733 or for any violation of this chapter or regulations adopted pursuant to

this chapter, in accordance with Sections 125.9, 148, and 4005 and the regulations adopted pursuant to those sections, and Health and Safety Code Sections 150200 through 150206.
(b) Where appropriate, a citation issued by the board, as specified in this section, may subject the person or entity to whom the citation is issued to an administrative fine.
(c) Notwithstanding any other provision of law, where appropriate, a citation issued by the board may contain an order of abatement. The order of abatement shall fix a reasonable time for abatement of the violation. It may also require the person or entity to whom the citation is issued to demonstrate how future compliance with the Pharmacy Law, and the regulations adopted pursuant thereto, will be accomplished. A demonstration may include, but is not limited to, submission of a corrective action plan, and requiring completion of up to six hours of continuing education courses in the subject matter specified in the order of abatement. Any continuing education courses required by the order of abatement shall be in addition to those required for license renewal.
(d) Nothing in this section shall in any way limit the board from issuing a citation, fine, and order of abatement pursuant to Section 4067 or Section 56.36 of the Civil Code, and the regulations adopted pursuant to those sections.

4315. (a) The executive officer, or his or her designee, may issue a letter of admonishment to a licensee for failure to comply with Section 733 or for failure to comply with this chapter or regulations adopted pursuant to this chapter, or Health and Safety Code Sections 150200 through 150206, directing the licensee to come into compliance.
(b) The letter of admonishment shall be in writing and shall describe in detail the nature and facts of the violation, including a reference to the statutes or regulations violated.
(c) The letter of admonishment shall inform the licensee that within 30 days of service of the order of admonishment the licensee may do either of the following:

(1) Submit a written request for an office conference to the executive officer of the board to contest the letter of admonishment.

(A) Upon a timely request, the executive officer, or his or her designee, shall hold an office conference with the licensee or the licensee's legal counsel or authorized representative. Unless so authorized by the executive officer, or his or her designee, no individual other than the legal counsel or authorized representative of the licensee may accompany the licensee to the office conference.
(B) Prior to or at the office conference, the licensee may submit to the executive officer declarations and documents pertinent to the subject matter of the letter of admonishment.
(C) The office conference is intended to be an informal proceeding and shall not be subject to the provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with Section 11400), and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code).
(D) The executive officer, or his or her designee, may affirm, modify, or withdraw the letter of admonishment. Within 14 calendar days from the date of the office conference, the executive officer, or his or her designee, shall personally serve or send by certified mail to the licensee's address of record with the board a written decision. This decision shall be deemed the final administrative decision concerning the letter of admonishment.

(E) Judicial review of the decision may be had by filing a petition for a writ of mandate in accordance with the provisions of Section 1094.5 of the Code of Civil Procedure within 30 days of the date the decision was personally served or sent by certified mail. The judicial review shall extend to the question of whether or not there was a prejudicial abuse of discretion in the issuance of the letter of admonishment.

(2) Comply with the letter of admonishment and submit a written corrective action plan to the executive officer documenting compliance. If an office conference is not requested pursuant to this section, compliance with the letter of admonishment shall not constitute an admission of the violation noted in the letter of admonishment.

(d) The letter of admonishment shall be served upon the licensee personally or by certified mail at the licensee's address of record with the board. If the licensee is served by certified mail, service shall be effective upon deposit in the United States mail.

(e) The licensee shall maintain and have readily available a copy of the letter of admonishment and corrective action plan, if any, for at least three years from the date of issuance of the letter of admonishment.

(f) Nothing in this section shall in any way limit the board's authority or ability to do either of the following:

(1) Issue a citation pursuant to Section 125.9, 148, or 4067 or pursuant to Section 1775 of Title 16 of the California Code of Regulations.

(2) Institute disciplinary proceedings pursuant to Article 19 (commencing with Section 4300).

B&P 4160 Wholesaler License Required

Amend Section 4160 & 4161 of the Business and Professions Code, to read:

4160. (a) A person may not act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.

(c) A separate license shall be required for each place of business owned or operated by a wholesaler. Each license shall be renewed annually and shall not be transferable.

(d) The board shall not issue or renew a wholesaler license until the wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of that designated representative. The designated representative-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. A wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge. A pharmacist may be identified as the designated representative-in-charge.

(e) A drug manufacturer premises licensed by the Food and Drug Administration or licensed pursuant to Section 111615 of the Health and Safety Code that only distributes dangerous drugs and dangerous devices of its own manufacture is exempt from this section and Section 4161.

(f) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. ~~A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct business as a wholesaler~~. A temporary license fee shall be $550 or another amount established by the board not to exceed the annual fee for renewal of a license to compound injectable sterile drug products. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the license holder or service by certified mail, return receipt requested at the license holder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary license nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary license holder be deemed to have a vested property right or interest in the license.
(g) This section shall become operative on January 1, 2006.

4161 a) A person located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state shall be considered a nonresident wholesaler.
(b) A nonresident wholesaler shall be licensed by the board prior to shipping, mailing, or delivering dangerous drugs or dangerous devices to a site located in this state.
(c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler from or through which dangerous drugs or dangerous devices are shipped, mailed, or delivered to a site located in this state. A license shall be renewed annually and shall not be transferable.
(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler, on renewal of a nonresident wholesaler license, or within 30 days of a change in that information:
(1) Its agent for service of process in this state.
(2) Its principal corporate officers, as specified by the board, if any.
(3) Its general partners, as specified by the board, if any.
(4) Its owners if the applicant is not a corporation or partnership.
(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.
(f) A nonresident wholesaler shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.
(g) A nonresident wholesaler shall maintain records of dangerous drugs and dangerous devices sold, traded, or transferred to persons in this state, so that the records are in a readily retrievable form.
(h) A nonresident wholesaler shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler license in this state shall include a license verification from the licensing authority in the applicant's state of residence.
(i) The board may not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.

(j) The designated representative-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. A nonresident wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge.
(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. ~~A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct business as a nonresident wholesaler.~~ A temporary license fee shall be $550 or another amount established by the board not to exceed the annual fee for renewal of a license to compound injectable sterile drug products. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the license holder or service by certified mail, return receipt requested at the license holder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary license nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary license holder be deemed to have a vested property right or interest in the license.
(l) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

B&P 4208 Intern Pharmacist License

Amend Section 4208 of the Business and Professions Code, to read:

4208. (a) At the discretion of the board, an intern pharmacist license may be issued for a period of:
(1) One to six years to a person who is currently enrolled in a school of pharmacy recognized by the board.
(2) Two years to a person who is a graduate of a school of pharmacy recognized by the board and who has applied to become licensed as a pharmacist in California.
(3) Two years to a foreign graduate who has met educational requirements described in paragraphs (1) and (2) of subdivision (a) of Section 4200.
(4) One year to a person who has failed the pharmacist licensure examination four times and has reenrolled in a school of pharmacy to satisfy the requirements of Section 4200.1.
(b) The board may issue an intern pharmacist license to an individual for the period of time specified in a decision of reinstatement adopted by the board.
(c) An intern pharmacist shall notify the board within 30 days of any change of address.
(d) An intern pharmacist whose license has been issued pursuant to paragraph (1) or paragraph (4) of subdivision (a) shall return his or her license, by registered mail, within 30 days of no longer being enrolled in a school of pharmacy. The intern pharmacist license will be canceled by the board. Notwithstanding subdivision (c), an intern pharmacist license may be reinstated if the student reenrolls in a school of pharmacy recognized by the board to fulfill the education requirements of paragraphs (1) to (4), inclusive, of subdivision (a) of Section 4200.

(e) Persons who have not completed experience requirements necessary to be eligible for the licensure examination may have their intern license extended for a period of up to two years at the discretion of the board if able to demonstrate their inability to exercise the privileges of the intern license during the initial license period.

ATTACHMENT 3

AB 2986 (Chapter 286, Statutes of 2006)
CURES Requirements
Language

Board of Pharmacy
Proposed Changes to AB 2986 (Chapter 286, Statutes of 2006)

CURES REPORTING

SECTION 1. Section 11162.1 of the Health and Safety Code is amended to read:
11162.1. (a) The prescription forms for controlled substances shall be printed with the following features:
(1) A latent, repetitive "void" pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.
(2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words "California Security Prescription."
(3) A chemical void protection that prevents alteration by chemical washing.
(4) A feature printed in thermo-chromic ink.
(5) An area of opaque writing so that the writing disappears if the prescription is lightened.
(6) A description of the security features included on each prescription form.
(7) (A) Six quantity check off boxes shall be printed on the form and the following quantities shall appear:
1–24
25–49
50–74
75–100
101–150
151 and over.
(B) In conjunction with the quantity boxes, a space shall be provided to designate the units referenced in the quantity boxes when the drug is not in tablet or capsule form.
(8) Prescription blanks shall contain a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."
(9) The preprinted name, category of licensure, license number, federal controlled substance registration number of the prescribing practitioner.
(10) Check boxes shall be printed on the form so that the prescriber may indicate the number of refills ordered.
(11) The date ~~of origin of~~ the prescription was written/ordered for the patient by the prescriber.
(12) A check box indicating the prescriber's order not to substitute.
(13) An identifying number assigned to the approved security printer by the Department of Justice.
(14) (A) A check box by the name of each prescriber when a prescription form lists multiple prescribers.
(B) Each prescriber who signs the prescription form shall identify himself or herself as the prescriber by checking the box by their name.
(b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.
(c) (1) A prescriber designated by a licensed health care facility, a clinic specified in Section 1200, or a clinic specified in subdivision (a) of Section 1206 that has 25 or more physicians or surgeons may order controlled substance prescription forms for use by prescribers when treating patients in that facility without the information required in paragraph (9) of subdivision (a) or paragraph (3) of this subdivision.

(2) Forms ordered pursuant to this subdivision shall have the name, category of licensure, license number, and federal controlled substance registration number of the designated prescriber and the name, address, category of licensure, and license number of the licensed health care facility, the clinic specified in Section 1200, or the clinic specified in subdivision (a) of Section 1206 that has 25 or more physicians or surgeons preprinted on the form.
(3) Forms ordered pursuant to this section shall not be valid prescriptions without the name, category of licensure, license number, and federal controlled substance registration number of the prescriber on the form.
(4) (A) Except as provided in subparagraph (B), the designated prescriber shall maintain a record of the prescribers to whom the controlled substance prescription forms are issued, that shall include the name, category of licensure, license number, federal controlled substance registration number, and the quantity of controlled substance prescription forms issued to each prescriber and be maintained in the health facility for three years.
(B) Forms ordered pursuant to this subdivision that are printed by a computerized prescription generation system shall not be subject to the requirements set forth in subparagraph (A) or paragraph (7) of subdivision (a). Forms printed pursuant to this subdivision that are printed by a computerized prescription generation system may contain the prescriber's name, category of professional licensure, license number, federal controlled substance registration number, and the date of the prescription.
~~(d) This section shall become operative on July 1, 2004.~~

SEC. 2. Section 11164 of the Health and Safety Code is amended to read:
11164. Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.
(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:
(1) The prescription shall be signed and dated by the prescriber in ink and shall contain the prescriber's address and telephone number; the patient's name ~~of the ultimate user~~ or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services; refill information, such as the number of refills ordered and whether the prescription ~~is a~~ is being filled initially or as ~~first-time request or~~ a refill; and the name, quantity, strength, and directions for use of the controlled substance prescribed.
(2) The prescription shall also contain the address of the person for whom the controlled substance is prescribed. If the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist shall write or type the address on the prescription or maintain this information in a readily retrievable form in the pharmacy.
(b) (1) Notwithstanding paragraph (1) of subdivision (a) of Section 11162.1, any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be produced in hard copy form and signed and dated by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. Any person who transmits, maintains, or receives any electronically transmitted prescription shall ensure the security, integrity, authority, and confidentiality of the prescription.

(2) The date of issue of the prescription and all the information required for a written prescription by subdivision (a) shall be included in the written record of the prescription; the pharmacist need not include the address, telephone number, license classification, or federal registry number of the prescriber or the address of the patient on the hard copy, if that information is readily retrievable in the pharmacy.
(3) Pursuant to an authorization of the prescriber, any agent of the prescriber on behalf of the prescriber may orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the written record of the prescription required by this subdivision specifies the name of the agent of the prescriber transmitting the prescription.
(c) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.
(d) Notwithstanding any provision of subdivisions (a) and (b), prescriptions for a controlled substance classified in Schedule V may be for more than one person in the same family with the same medical need.
~~(e) This section shall become operative on January 1, 2005.~~

SEC. 3. Section 11165 of the Health and Safety Code is amended to read:
11165. (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.
(b) The reporting of Schedule III and Schedule IV controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The Department of Justice may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, the Naturopathic Doctor's Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III and Schedule IV controlled substance prescriptions to CURES.
(c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party.
(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, the dispensing pharmacy shall provide the following information to the

Department of Justice on a weekly basis each Monday for the preceeding week (Monday through Sunday), and in a format specified by the Department of Justice:
(1) Full name~~,~~ and address~~, and the telephone number~~ of the ~~ultimate user~~ patient or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.
(2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.
(3) Pharmacy prescription number, license number, and federal controlled substance registration number.
(4) NDC (National Drug Code) number of the controlled substance dispensed.
(5) Quantity of the controlled substance dispensed.
(6) ICD-9 (diagnosis code), if available.
(7) Number of refills ordered.
(8) Whether the drug was dispensed initially from a prescription or as a refill ~~of a prescription or as a first-time request~~.
(9) Date of origin of the prescription.
(10) Date of dispensing of the prescription.
~~(e) This section shall become operative on January 1, 2005.~~

SEC. 4. Section 11165.1 of the Health and Safety Code is amended to read:
11165.1. (a) (1) A licensed health care practitioner eligible to prescribe Schedule II, Schedule III, or Schedule IV controlled substances or a pharmacist may make a written request for, and the Department of Justice may release to that practitioner or pharmacist, the history of controlled substances dispensed to an individual under his or her care based on data contained in CURES.
(2) Any request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the Department of Justice.
(b) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, or Schedule IV controlled substances, the Department of Justice may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.
(c) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the Department of Justice pursuant to this section shall be considered medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

SEC. 5. Section 11190 of the Health and Safety Code is amended to read:
11190. (a) Every practitioner, other than a pharmacist, who prescribes or administers a controlled substance classified in Schedule II shall make a record that, as to the transaction, shows all of the following:
(1) The name and address of the patient.
(2) The date.
(3) The character, including the name and strength, and quantity of controlled substances involved.
(b) The prescriber's record shall show the pathology and purpose for which the controlled substance was administered or prescribed.

(c) (1) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance that is dispensed by a prescriber pursuant to Section 4170 of the Business and Professions Code, the prescriber shall record and maintain the following information:
(A) Full name, address, and the telephone number of the patient ~~ultimate user~~ or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the patient.
(B) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.
(C) NDC (National Drug Code) number of the controlled substance dispensed.
(D) Quantity of the controlled substance dispensed.
(E) ICD-9 (diagnosis code), if available.
(F) Number of refills ordered.
(G) Whether the drug was dispensed as a refill of a prescription or as a first-time request.
(H) Date ~~of origin of~~ the prescription was ordered for the patient by the prescriber.
(2) (A) Each prescriber that dispenses controlled substances shall provide the Department of Justice the information required by this subdivision on a weekly basis in a format set by the Department of Justice pursuant to regulation.
(B) The reporting requirement in this section shall not apply to the direct administration of a controlled substance to the body of an ultimate user.
~~(d) This section shall become operative on January 1, 2005.~~
(e) The reporting requirement in this section for Schedule IV controlled substances shall not apply to any of the following:
(1) The dispensing of a controlled substance in a quantity limited to an amount adequate to treat the ultimate user involved for 48 hours or less.
(2) The administration or dispensing of a controlled substance in accordance with any other exclusion identified by the United States Health and Human Service Secretary for the National All Schedules Prescription Electronic Reporting Act of 2005.
(f) Notwithstanding paragraph (2) of subdivision (c), the reporting requirement of the information required by this section for a Schedule II or Schedule III controlled substance, in a format set by the Department of Justice pursuant to regulation, shall be on a monthly basis for all of the following:
(1) The dispensing of a controlled substance in a quantity limited to an amount adequate to treat the ultimate user involved for 48 hours or less.
(2) The administration or dispensing of a controlled substance in accordance with any other exclusion identified by the United States Health and Human Service Secretary for the National All Schedules Prescription Electronic Reporting Act of 2005.

SEC. 6. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

ATTACHMENT 4

Meeting Summary January 8, 2007
Legislation and Regulation Committee

MEETING SUMMARY
LEGISLATION AND REGULATION COMMITTEE
DATE: January 8, 2007
LOCATION: Department of Consumer Affairs
1625 N Market Blvd
Sacramento, CA 95834

BOARD MEMBERS PRESENT:

Ken Schell, PharmD, Acting Chair
Tim Dazé
Henry Hough

BOARD STAFF PRESENT:

Virginia Herold, Interim Executive Officer
Robert Ratcliff, Supervising Inspector
Anne Sodergren, Legislation and Regulation Manager

Chairperson Schell called the meeting to order at 9:32 a.m.

Approved Regulations

Dr. Schell stated that two regulations were recently approved by the Office of Administrative Law.

1. The "Tech Check Tech" regulation, which amends 1793.7 and adds 1793.8, became effective January 5, 2007.

   This regulation allows for and defines the conditions under which a specially trained pharmacy technician may check the work of another pharmacy technician in an acute care pharmacy setting.

   Interim Executive Officer Herold advised the committee that Cedars Sinai Hospital issued a Press Release regarding the Tech Check Tech regulation and its contributions to patient safety by redirecting pharmacists to clinical areas within the hospital.

   It was recommended that a FAQ be developed on the regulation to reiterate that the regulation only applies to acute care hospitals, along with other items generating questions to the board.

   Discussion included questions about how the board will enforce this regulation and whether the regulation should be amended to set a

minimum performance level for the technicians completing the second check.

2. The Automated Delivery Device regulation, which repeals 16 CCR 1717(e) and amends 16 CCR 1713, will take effect January 26, 2007.

   These changes will allow pharmacy patients the ability to use a vending-like machine located near the pharmacy to obtain their refill medication if they choose to do so. This regulation also allows the use of a prescription drop-off box outside the pharmacy as a means to leave a prescription for a pharmacy to later fill.

   Interim Executive Officer Herold indicated that the board will routinely check for problems during the course of routine and complaint inspections and reiterated that the pharmacy is responsible for the security of the drop box and delivery device.

Board Adopted Regulations

The committee was advised that two regulations recently adopted by the board at the October Board Meeting are currently undergoing administrative review.

1. The repeal of 16 CCR 1717.2 was just approved by the Department of Consumer Affairs and will be forwarded to the Office of Administrative Law.

   The repeal of this section removes a barrier that prevents pharmacists in some circumstances from having full knowledge of all prescription drugs a patient is taking. The repeal of this section will result in better patient care without compromising patient medical record privacy.

2. The addition of CCR 1784 is still under review by the Department.

   The adoption of this section establishes a self-assessment form for wholesalers and the requirement of the designated representative-in-charge to complete this form to ensure compliance with pharmacy law. This form will also aid wholesalers in complying with legal requirements of wholesaler operations and therefore increase public safety as a result of this compliance.

The committee posed questions about the timeframe to complete a rulemaking file and staff provided a brief overview of the process and the current turn around time for department review.

Board Approved Regulations Currently Noticed

The committee was advised that two regulations are currently noticed.

1. Amendment to 16 CCR 1706.2

   In 1997, the board established the provisions of 1706.2 to define when an application for a pharmacy, manufacturer, supplier, clinic, medical device retailer, or warehouse of a medical device retailer, had been abandoned. In 2005, the board updated this regulation to add non-resident pharmacy, sterile injectable compounding pharmacy to the regulation and to delete the terms, manufacturer, supplier, medical device retailer, and warehouse of a medical device retailer. This proposed regulation change would update the regulation to add veterinary food-animal drug retailer, hypodermic needles and syringes, pharmacist interns and designated representatives to the regulation.

   The comment period for this proposal will close on February 5, 2007.

2. Amendment to 16 CCR 1775.4

   The Board of Pharmacy proposes to amend Section 1775.4 of Division 17 of Title 16 of the California Code of Regulations. The purpose for amending the regulation is to limit the number of times a person or entity can reschedule an informal office conference. Currently there is no provision to allow for a person or entity to reschedule the informal office conference once scheduled. This proposal would afford a person or entity the right to request that the informal office conference be rescheduled one time.

   The comment period for this proposal will close on February 5, 2007.

According to Department of Consumer Affair's Legal Office, the board may take action on the two pending regulations at the January 2007 Board Meeting as long as a motion is made to adopt the regulations as noticed and no negative comments or substantive changes are recommended.

Discussion included whether the board has the latitude to reschedule the informal office conference referenced in CCR 1775.4 without it counting as a cancellation. Staff will follow up with staff counsel to confirm the language as noticed will allow for this.

MOTION: Recommend that the board adopt of these two regulations at the January 2007 Board Meeting to ensure the timely processing of the rulemaking file and delegate to staff to compile the rulemaking file. If negative comments are received before the close of the comment

period, staff is to return the regulation to the board for consideration at the April 2007 Board Meeting.

Board Approved Regulations Awaiting Notice

1. Section 100 Changes

The committee discussed previously approved Section 100 regulation changes as well as the process involved in completing this type of rulemaking. Section 100 or rulemaking without regulatory impact changes are made to keep the regulations consistent with statutes. This is an expedited process without a formal notice process.

Items to be included in this rulemaking include, amendment to CCR 1709.1, CCR 1780, CCR 1780.1 and 1781 and CCR 1786. Interim Executive Officer Herold summarized each proposal and discussed the need for each of the changes.

2. Disciplinary Guidelines

The committee was advised that modifications were being made to the Disciplinary Guidelines that will be brought to the April 2007 Board Meeting.

3. California Building Standards

At the April 2006 Board Meeting, the board agreed to request amendments to California Building Code regarding provisions for compounding of injectable medicine from nonsterile components to contain provisions currently required in California Business and Profession Code. Interim Executive Officer Herold provided a brief history and overview of the rulemaking process to modify the California Building Standards Code including that staff will now need to convert these changes into a new format to comply with the Building Standards Commissions' new process and will re-notice the proposal.

Discussion included how the board is notified of changes to the Building Code that the board does not initiate and who is responsible to ensure consistency between requirements in pharmacy law and those found in Building Standards Code.

Supervising Inspector Ratcliff explained that inspectors confirm compliance during routine inspections and complaint investigations. Interim Executive Officer Herold also stated that the Building Standards Commission must also check with the board in advance of making changes that would affect board licensees. Additionally, the board

receives inquiries from architects and others regarding building requirements.

Board Approved Regulations – Proposed Language to be Developed

1. Process and Criteria to Approve Accreditation Agencies for Pharmacies.

   This regulation would formalize criteria the board uses to approve such agencies and would remove the administrative burden placed on the board for such approvals.

   The committee was provided with a summary of this proposal. Staff will develop the draft language in concert with staff counsel to be provided a future committee meeting for consideration.

2. Notice to Consumers

   The committee was advised that at the next Communication and Public Education Committee Meeting a final draft of the revised Notice to Consumers poster (to make the wording compliant with requirements of AB 2583 (Nation, Chapter 487, Statutes of 2006) regarding a patient's right to lawfully obtain prescribed medications from a pharmacy) will be discussed. Upon approval by the board, this notice will need to be incorporated into CCR 1707.2 in a future rulemaking.

Proposed Legislation

1. Omnibus Provisions

   The committee reviewed omnibus provisions previously approved by the board to be introduced this legislative cycle. These provisions include amendments to the following:

   B & PC 4084 – Adulterated or Counterfeit Drugs or Dangerous Devices
   B & PC 4162 and 4162.5 – Wholesaler Bonding Requirements
   B & PC 4314 and 4315 – Citation and Fine for Repository and Distribution Programs for Dangerous Drugs
   B & PC 4160(f) and 4161(k) – Temporary License Fee for Wholesalers
   B & PC 4208 – Intern Pharmacist License

   Interim Executive Officer Herold summarized each proposal as well as the need for each of the changes. At the October Legislation and Regulation Committee Meeting, staff had recommended revisions to B & PC 4312, but after further review and discussion, removed this request.

Ms. Herold explained what constitutes an omnibus provision and indicated that the board has an author to carry this legislation.

2. Changes to CURES enacted by AB 2986 (Chapter 286, Statues of 2006)

Interim Executive Officer Herold provided an overview of the implementation issues arising from changes enacted in 2006 to the CURES program expanding reporting requirements to include Schedule IV controlled substances. In addition, the legislation expanded the reporting elements to include a patient's phone number and increased the frequency with which this data must be submitted. Staff is proposing a transition period for implementation of the new reporting requirements for CURES.

An article is included in the newest version of *The Script*, which will provide information to licensees about the board's intent to enforce these new CURES requirements via an educational emphasis for the first six to 12 months.

Discussion from the public included frustration on the part of pharmacies who are receiving unclear information from the DOJ about the expansion as well as new software standards that are required, but are not included in the legislation.

A representative from the DOJ indicated that they are receiving a lot of calls from individuals about the new requirements. The DOJ is currently working the contractor responsible for accepting the data to ensure conformity with these new requirements, but a new contract has not been obtained.

A concern was expressed that the board will be aggressively enforcing this new requirement. Interim Executive Officer Herold responded that the board intends to take a transitional and educational approach with licensees. Supervising Inspector Ratcliff reiterated that board inspectors will provide guidance, not aggressive enforcement to ensure compliance for the first six to 12 months.

Discussion also surrounded a recommendation to pursue emergency legislation to achieve some of these changes because of a potential violation of HIPAA. Interim Executive Officer indicated that it may not be possible to demonstrate the urgency and that to be successful a coalition would need to advocate for the change.

Comments from the public indicated that the proposed changes make the requirements clear however there is still an outstanding issue about the

inconsistency between state and federal classifications of some drugs, and which schedule determines if a drug should be reported to CURES.

Interim Executive Officer Herold that staff will seek input from counsel.

The DOJ indicated that they hope to have pharmacies compliant with the new ASAP software requirements by July 2007.

A representative from Longs expressed concern about the ASAP software requirements as they had not been made aware of the requirement.

MOTION: Recommend to pursue changes with the understanding that staff will continue to work on the language with interested stakeholders.

3. Licensing of Headquarters for Chain Pharmacies

Interim Executive Officer Herold explained that the board currently has an informal process already established for chain store pharmacies, to renew and purchase pharmacies; however the law does not recognize the construct of "headquarters." This could be considered an underground regulation. This proposal would authorize a headquarter to enable a chain to renew 15 to 800 licenses all at one time, which greatly simplifies processing for licensees as well as the board.

Dr. Schell indicated that the proposal seemed reasonable but expressed concern that the board could potentially revoke a headquarters license. Ms. Herold explained that currently a headquarters is more of a convenience. If the board were to discipline a headquarters, if would do so. If revocation were pursued, it would mean revocation of all pharmacies in the state owned by the Corporation. The board has the authority to do this now; it would just have to be done on a store by store basis.

Board staff will continue to explore this issue and will present a recommendation at a future committee meeting if appropriate.

Proposed Regulations

1. Section 100 Rulemaking without Regulatory Effect

Board staff presented two additional Section 100 changes for committee consideration: amend CCR 1715 – Self Assessment Forms to update changes in pharmacy law since the last revision of this form, and amend CCR 1793.8. This section currently references Business and Professions Code section 4052, however because of recodification of this section

included in Assembly Bill 2408 (Chapter 777, Statutes of 2006) this reference requires correction.

MOTION: Recommend the board accept these proposals at the January 2007 board meeting.

2. Proposed Addition to CCR 1785 – Self Assessment of a Veterinary Food-Animal Drug Retailer.

   The adoption of Section 1785 of the California Code of Regulations would establish a self-assessment process for veterinary food-animal drug retailers and require the designated representative-in-charge to complete this form to ensure compliance with California law. This form would also aid these licensees in complying with legal requirements of their operations and therefore increase public safety as a result of this compliance.

MOTION: Recommend the board approve this proposal at the January 2007 board meeting.

Public Requests for Future Legislation and Regulatory Proposals

1. Supervising Inspector Ratcliff requested the committee to consider an amendment to CCR 1707.3. Currently this regulation requires a drug utilization review on a new prescription. The recommendation proposed would require this review on all prescriptions, new or refill.

   Supervising Inspector Ratcliff reiterated that this proposal is not to require consultation on all prescriptions, rather just that a drug utilization review be completed in advance of dispensing the medication.

   Comments from the pubic indicate that several organizations already do this.

2. Steve Gray suggested that the board repeal the section of the Health and Safety Code that requires the board to approve a pharmacy's computer system for controlled substances.

   Staff will work on this proposal with Dr. Gray and bring it to the next Legislation and Regulation Committee Meeting.

3. Steve Gray requires that the board pursue legislation that would require that a criminal background check be required on a pharmacy technician trainee.

Interim Executive Officer Herold requested that Mr. Gray provide a draft of his proposal for consideration.

4. Interim Executive Officer Herold proposed that the board consider developing a protocol consistent with CDC guidelines for pharmacists to provide immunizations for flu vaccines according to a state protocol developed as a regulation, similar to the process used for the emergency contraception state protocol.

   Discussion on this topic included that this would be important in response to a disaster and that a coalition may need to be formed to ensure the success of this proposal.

New Business

Dr. Gray requested clarification of a new law that allows a physician to write a prescription for a patient's partner with a communicable disease. Dr. Gray asked for guidance on how this law will be implemented specifically for how to label the container for the partner and suggested that a newsletter article discussing this topic would be valuable.

Adjournment

The committee adjourned at 11:55 a.m.

ATTACHMENT 5

Meeting Summary October 25, 2006
Legislation and Regulation Committee

MEETING SUMMARY
LEGISLATION AND REGULATION COMMITTEE
DATE: October 25, 2006
LOCATION: Sheraton Gateway San Francisco Airport Hotel
600 Airport Blvd.
Burlingame, CA 94010

BOARD MEMBERS PRESENT:
Andrea Zinder, Chair
Ken Schell, PharmD
Tim Dazé
Henry Hough

BOARD STAFF PRESENT:

Virginia Herold, Interim Executive Officer
Robert Ratcliff, Supervising Inspector
Anne Sodergren, Legislation and Regulation Manager

Chairperson Zinder called the meeting to order at 3:30 p.m.

Proposed Legislation

Proposed omnibus provisions were provided for consideration and approval to be introduced in the upcoming legislative cycle.

1. **Omnibus Provisions**
The committee reviewed omnibus provisions previously approved by the board to be introduced this legislative cycle. These provisions include amendments to the following:
   a. **B & PC 4084 – Adulterated or Counterfeit Drugs or Dangerous Devices**
   To allow board inspectors to embargo a prescription drug when the inspector has probable cause that it is misbranded.
   b. **B & PC 4162 and 4162.5 – Wholesaler Bonding Requirements**
   Extend bonding requirements for wholesalers from 2011 to 2015 to match the extension given to implement the e-pedigree requirements, restoring provisions in SB 1476 chaptered out by SB 1475.
   c. **B & PC 4314 and 4315 – Citation and Fine for Repository and Distribution Programs for Dangerous Drugs**
   Allow the board to cite and fine licensees for violations of Health and Safety Code sections 150200-150206 which authorize a county

to establish by local ordinance, a repository and distribution program for specified unused medications from skilled nursing homes to medically indigent patients served by government-owned pharmacies.

d. **B & PC 4160(f) and 4161(k) – Temporary License Fee for Wholesalers**
Revise section to specify temporary license fee of $550. Current law does not specify the temporary fee.

e. **B & PC 4208 – Intern Pharmacist License**
Revise requirements for intern licenses to allow the board the discretion to extend the duration of an intern license.

Staff counsel recommended that the proposed language in B & PC 4208 expand to include the general circumstances when the extension of the intern license would occur.

MOTION: Recommend that the board approve the proposed language to be included in the omnibus bill.

Proposed Regulations

Board staff presented a Section 100 - Rulemaking without Regulatory Effect change for committee consideration

Amend CCR 1715 – Self Assessment Forms

This amendment is to update changes in pharmacy law since the last revision of this form.

MOTION: Recommend that the board approve the proposal at the January 2007 Board Meeting.

Public Requests for Future Legislation and Regulatory Proposals

1. Deputy Attorney General Room suggested an amendment to Business and Professions Code section 4312 to allow the board the ability to void a board issued business license to when the business appears to be closed.

   Board staff will draft language for consideration at the next board meeting.

No additional proposals were presented.

Dr. Gray requested clarification about whether a hospital can provide drugs to an ambulance and can a company that takes charge of a corpse receive and

administer medications to ensure the viability of organs for transplant. Dr. Gray agreed to have someone come to the next committee meeting to further discuss these topics as well as the need for possible legislation.

Adjournment

The committee adjourned at 5:00 p.m.